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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,300	06/15/2001	Lieven De Veylder	2364/300 (C 2681 US)	7567

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EXAMINER

COLLINS, CYNTHIA E

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 01/29/2003

60

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/868,300

Applicant(s)

DE VEYLDER ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 and 41-46 is/are pending in the application.
- 4a) Of the above claim(s) 2,3,11,12,24-34 and 41-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-10 and 13-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1, 4-10, 14-23, and SEQ ID NOS:7 and 8, in Paper No. 9 is acknowledged. The traversal is on the ground(s) that the special technical feature linking the inventions of Groups I-X is not a DNA sequence encoding a cell cycle interacting protein, but the elected sequences of SEQ ID NOS:7 and 8 (reply page 4). The traversal is also on the ground(s) that the sequences of Groups (A) and (B) and (H) to (L) are novel, and alternatively, the sequences of Groups (B)-(G) are related to each other and represent PHO80-like proteins (reply page 5). This is not found persuasive because the claims as originally presented are not limited to SEQ ID NOS:7 and 8, but are directed to multiple sequences encoding groups of structurally and functionally unrelated proteins. Accordingly, while SEQ ID NOS:7 and 8 constitute the special technical feature of the elected invention, SEQ ID NOS:7 and 8 cannot constitute a special technical feature that links the nonelected groups of inventions. This is also not found persuasive because while each of Groups (A) and (B) and (H) to (L) may be novel, the groups do not share a common activity and a common significant structural element that is a contribution over the prior art and thus are not linked by a special technical feature. While the sequences of Groups (B)-(G) may be related to each other and represent PHO80-like proteins, sequences encoding PHO80 proteins are known in the art, and thus cannot constitute a special technical feature linking the groups of inventions (see for example Madden et al., GenBank Accession No. X07464, 12 September 1993). Additionally, claim 13, which was inadvertently omitted from the restriction requirement, is directed to the subject matter of Group I and is therefore also included in Group I. Claims 2-3, 11-12, 24-34 and 41-46, and the

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nonelected sequences, are withdrawn from consideration as being directed to nonelected inventions.

The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

Claim 1 is objected to because it recites the sequences of nonelected inventions.

Appropriate correction is required.

Claim 4 is objected to because it depends from claims directed to nonelected inventions.

Appropriate correction is required.

Specification

This application does not contain an abstract of the disclosure as required by 37

CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4 and 5, and claims 6-10 and 13-23 dependent thereon, are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 is drawn to a DNA sequence encoding a cell cycle interacting protein or encoding an immunologically active and/or functional fragment of such a protein comprising a

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nucleotide sequence encoding at least the mature form of a protein (VB89) comprising (dc) a nucleotide sequence hybridizing with the complementary strand of SEQ ID NO:7 or a nucleic acid encoding SEQ ID NO:8 under stringent hybridization conditions, (dd) a nucleotide sequence encoding a protein having an amino acid sequence at least 60% identical to the amino acid sequence of SEQ ID NO:8, and (de) a nucleotide sequence encoding at least the domain binding to CDKs of the protein encoded by the nucleotide sequence of (da) to (dd). Claim 4 is broadly drawn to any DNA sequence encoding any cell cycle interacting protein obtained by using a two-hybrid screening assay wherein CDC2a or CDC2b is used as bait and a plant cell suspension cDNA library is used as prey. Claim 5 is drawn to a nucleic acid molecule at least 15 nucleotides in length hybridizing specifically with a DNA sequence of claim 1.

The specification describes 7 different types of DNA sequences obtained from an *Arabidopsis thaliana* plant cell suspension cDNA library encoding structurally different groups of polypeptides that interact with CDC2a or CDC2b in a two-hybrid screening assay, including the elected DNA sequence of SEQ ID NO:7 (pages 69-102). The specification also describes the elected DNA sequence of SEQ ID NO:7 as encoding a polypeptide corresponding to a partial open reading frame having an amino acid sequence of SEQ ID NO:8, said polypeptide interacting with CDC2bAt but not CDC2aAt in a yeast two-hybrid system, and said polypeptide exhibiting amino acid sequence homology to HAL3 of *Saccharomyces cerevisiae* (page 72). The specification does not describe or characterize any nucleotide sequence hybridizing with the complementary strand of SEQ ID NO:7 or a nucleic acid encoding SEQ ID NO:8 under stringent hybridization conditions, any nucleotide sequence encoding a protein having an amino acid sequence at least 60% identical to the amino acid sequence of SEQ ID NO:8, any nucleotide sequence encoding at least the domain binding to CDKs of the protein encoded by the nucleotide

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sequence of (da) to (dd), or any nucleic acid molecule at least 15 nucleotides in length hybridizing specifically with a DNA sequence of claim 1.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." *Id.*

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus as broadly claimed. Given the lack of written description of the claimed products, any method of using them would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing. See Written Description Requirement guidelines published in Federal Register/ Vol. 66, No.4/ Friday January 5, 2001/Notices: pp. 1099-1111).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1, 4, 9, 10, 18, 19 and 22, and claims 5-10, 13-17, 20-21 and 23 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 4, 10 and 19 are indefinite in the recitation of “cell cycle interacting protein”. It is unclear what function the protein exhibits, as the nature of the specific interaction is not specified, and the relationship between the protein and the cell cycle is unclear.

Claim 1 is indefinite in the recitation of “VB89”. It is unclear what the acronym “VB89” designates.

Claim 1 is indefinite in the recitation of “stringent hybridization conditions”. It is unclear what constitutes “stringent hybridization conditions”, as those skilled in the art define the term differently.

Claim 1 is indefinite in the recitation of “CDKs”. It is unclear what the acronym “CDKs” designates.

Claim 18 is indefinite in the recitation of “enhanced”, as “enhanced” is a relative term lacking a comparative basis.

Claim 18 is indefinite in the recitation of “environmental stress”. It is unclear what types of stress are encompassed by the claim, as any aspect of the environment can impose stress on a plant.

Claim 22 is indefinite in the recitation of “deficiency”, as “deficiency” is a relative term lacking a comparative basis.

Claim Rejections - 35 USC § 101 and 35 USC § 112

Claims 1 and 4-5 are rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1 and 4-5, as written, do not sufficiently distinguish over DNA sequences as they exist naturally because the claims do not particularly point out any non-naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See Diamond v. Chakrabarty, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of “Isolated” or “Purified”.

Claims 1, 4-10, and 13-23 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The claims are drawn to a DNA sequence encoding a cell cycle interacting protein or encoding an immunologically active and/or functional fragment of such a protein comprising a nucleotide sequence encoding at least the mature form of a protein (VB89) comprising the amino acid sequence given in SEQ ID NO:8, the nucleotide sequence as given in SEQ ID NO:7, a nucleotide sequence hybridizing with the complementary strand of SEQ ID NO:7 or a nucleic acid encoding SEQ ID NO:8 under stringent hybridization conditions, a nucleotide sequence encoding a protein having an amino acid sequence at least 60% identical to the amino acid sequence of SEQ ID NO:8, and a nucleotide sequence encoding at least the domain binding to CDKs of the protein encoded by the aforesaid nucleotide sequences, a nucleic acid molecule at least 15 nucleotides in length hybridizing specifically with a DNA sequence of claim 1, a vector,

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a host cell, a method for the production of a cell cycle interacting protein, a method for the production of transgenic plants, a transgenic plant, including a transgenic plant in which cell division and/or growth is enhanced and/or wherein the plant is less sensitive to environmental stress plant cell or plant tissue.

The specification discloses an isolated nucleic acid of SEQ ID NO:7 obtained from *Arabidopsis thaliana* that encodes a polypeptide corresponding to a partial open reading frame having an amino acid sequence of SEQ ID NO:8, said polypeptide interacting with CDC2bAt but not CDC2aAt in a yeast two-hybrid system, and said polypeptide exhibiting amino acid sequence homology to HAL3, a protein encoded by a halotolerance gene of *Saccharomyces cerevisiae* (page 72). The specification also suggests that the claimed nucleic acid may be useful for conferring salt tolerance to a plant or for improving plant growth under saline conditions (pages 72-73). The specification does not disclose a specific function for the polypeptide encoded by SEQ ID NO:7, and the specification does not disclose the effect of transforming a plant or cell with the claimed DNA sequence.

First, the claims do not recite a specific function for the claimed DNA sequence or the polypeptide it encodes. The claimed invention lacks utility because no specific function has been demonstrated for the polypeptide encoded by the claimed DNA sequence. Although the specification reveals SEQ ID NO:7 encodes a polypeptide having amino acid sequence homology to HAL3, a protein encoded by a halotolerance gene of *Saccharomyces cerevisiae*, no empirical data is provided to support a function for the protein encoded by SEQ ID NO:7. While empirical data is not required for patentability, the state of the art recognizes that while a functional assignment based on sequence comparisons may categorize a protein into a particular class of proteins or provide a starting point for verifying protein activity, it does not replace

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empirical data for confirming protein activity, as structural homology between amino acid sequences is not always predictive of their functional homology. For example, Doerks et al. teach that incorrect or incomplete sequence information within a database affects the predictive capacity of the database (Trends in Genetics, June 1998, Vol. 14, No. 6, pages 248-250, see page 248 column 1 paragraph 1). Doerks et al. also teach that query searches may identify shared homology with multiple groups of functionally unrelated proteins (Page 248 column 3 second full paragraph), that regions of shared homology may be nonfunctional regions (Page 248 column 3 third full paragraph), and that the degree of shared homology within a functional region does not always predict a conservation of the functional mechanism of that region (Page 248 column 3 fourth full paragraph).

Second, Applicant's claimed DNA sequence lacks substantial utility under current utility guidelines. While the specification implies that the claimed DNA sequence is useful for conferring salt tolerance to a plant or for improving plant growth under saline conditions, the specification does not disclose a halotolerance function for the polypeptide encoded by SEQ ID NO:7, and the specification does not disclose the effect of expressing the claimed DNA sequence in any plant, tissue or cell. Applicant does not teach how the claimed DNA sequence or its encoded polypeptide would be substantially beneficial to the public. Although DNA sequences encoding polypeptides of known function may have a well established utility, DNA sequences encoding polypeptides of unknown function do not. It is apparent that extensive further research, not considered to be routine experimentation, would be required before one of skill in the art would know how to use the claimed invention. It has been established by the courts that a utility which requires or constitutes carrying out further research to identify or reasonably confirm a "real world" context of use is not a substantial utility.

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"The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point--where specific benefit exists in currently available form--there is insufficient justification for permitting an applicant to engross what may prove to be a broad field." (Brenner v. Manson, 383 U.S. 519 (1966)).

Thus, while a DNA sequence able to confer halotolerance has substantial benefit to the public, Applicant does not disclose that SEQ ID NO:7 encodes such a polypeptide, and one skilled in the art cannot conclude that SEQ ID NO:7 encodes a polypeptide with a halotolerance function based upon Applicant's disclosure. Applicant's invention is not refined to the point where specific benefit exists in currently available form. As set forth above, one skilled in the art cannot readily take Applicant's claimed invention and derive immediate benefits from it based upon Applicant's disclosure. Accordingly, the claimed invention lacks a real world use. (see Utility Examination Guidelines published in the Federal Register, Vol. 66, No. 4, Friday, January 5, 2001, Notices, pages 1092-1099).

Claims 1, 4-10, and 13-23 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 4-10 are rejected under 35 U.S.C. 102(B) as being anticipated by De Veylder et al. (FEBS Letters, 1997, Vol. 412, pages 446-452).

The claims are drawn to a DNA sequence encoding a cell cycle interacting protein or encoding an immunologically active and/or functional fragment of such a protein comprising a nucleotide sequence hybridizing with the complementary strand of SEQ ID NO:7 or a nucleic acid encoding SEQ ID NO:8 under stringent hybridization conditions, and a nucleotide sequence encoding at least the domain binding to CDKs of the protein encoded by the aforesaid nucleotide sequences, a nucleic acid molecule at least 15 nucleotides in length hybridizing specifically with a DNA sequence of claim 1, a vector, a host cell, a DNA sequence encoding a cell cycle interacting protein obtained by using a two-hybrid screening assay wherein CDC2a or CDC2b is used as bait and a plant cell suspension cDNA library is used as prey, and a method for the production of a cell cycle protein.

De Veylder et al. teach a DNA sequence encoding an *Arabidopsis* Cks1At cell cycle protein obtained by using a two-hybrid screening assay wherein CDC2aAt was used as bait (page 448 Figures 1 and 2). While De Veylder et al. teach the use of plant vegetative tissues rather than a plant cell suspension as the source of the cDNA library used as prey, the source of the cDNA library used as prey does not distinguish the claimed DNA sequence from the DNA sequence taught by De Veylder et al., as the source of the cDNA library used as prey does not determine the structure or function of the DNA sequences obtained therefrom. While De Veylder et al. do not teach a DNA sequence of SEQ ID NO:7 or a DNA sequence encoding SEQ ID NO:8, the DNA sequence taught by De Veylder et al. would nonetheless necessarily hybridize with SEQ

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ID NO:7 or a nucleic acid encoding SEQ ID NO:8 or nucleic acid molecule at least 15 nucleotides in length, as the hybridization conditions are undefined. Additionally, the DNA sequence taught by De Veylder et al. would inherently encode at least the domain binding to CDKs, as CKS proteins are known to bind to CDKs. De Veylder et al. also teach a vector and a host cell (page 449 Figure 4). Additionally, De Veylder et al. teach a method for the production of a Cks1At cell cycle protein (page 450 paragraph spanning columns 1 and 2).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4-10 and 13-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doerner et al. (Nature, April 1996, Vol. 380, pages 520-523) in view of De Veylder et al. (FEBS Letters, 1997, Vol. 412, pages 446-452).

The claims are drawn to a method for the production of transgenic plants comprising introducing a DNA sequence of claim 1 encoding a cell cycle interacting protein into the genome of a plant and regenerating a plant. The claims are also drawn to transgenic plants produced by said method, including plants in which cell division and/or growth is enhanced, plants in which expression of the transgene leads to a reduction in the synthesis of a cell cycle interacting protein and which display a deficiency in plant cell division and/or growth.

Doerner et al. teach a method for the production of transgenic plants comprising introducing a DNA sequence encoding an *Arabidopsis* Cyc1At cyclin cell cycle interacting protein into the genome of an *Arabidopsis* plant cell and regenerating an *Arabidopsis* plant (page 522 column 1). Doerner et al. et al. also teach that transgenic *Arabidopsis* plants produced by said method exhibit an increase in root growth rate (page 523 Figure 3).

Doerner et al. do not teach a DNA sequence of claim 1, or plants in which expression of a transgene leads to a reduction in the synthesis of a cell cycle interacting protein and which display a deficiency in plant cell division and/or growth.

The teachings of De Veylder et al. are discussed *supra*.

Given the success of Doerner et al. in producing transgenic plants in which cell division and/or growth is enhanced by transforming said plants with a DNA sequence encoding a cell cycle interacting protein, and given that De Veylder et al. teach a DNA sequence of claim 1 encoding a cell cycle interacting protein, it would have been *prima facie* obvious to one skilled in the art at the time the invention was made to use the method taught by Doerner et al. to make a transgenic plant in which cell division and/or growth is enhanced by transforming a plant with a DNA sequence of claim 1 encoding a cell cycle interacting protein, without any surprising or unexpected results. Furthermore, given that techniques such as antisense, sense, ribozyme, cosuppression, etc. were known in the art at the time of Applicant's invention, the use of such techniques to achieve an opposite phenotype (deficiency in plant cell division and/or growth) would have been an obvious modification of method design parameters. Accordingly, one skilled in the art would have been motivated to generate the claimed invention with a reasonable expectation of success. Thus, the claimed invention would have been *prima facie* obvious as a

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whole to one of ordinary skill in the art at the time the invention was made. Seed propagation of desirable genotypes is well known.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
January 25, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180/1638

